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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/356,229	12/19/94	NILSSON	K 06/87-50439

EXAMINER

18M2/1209
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ART UNIT	PAPER NUMBER
1802	17

NGUYEN, B

DATE MAILED: 12/09/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/12/97 & 8/25/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-21 ~~is~~/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-21 ~~is~~/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Applicant's amendment filed 8/25/97 has been received. Claims 17-21 have been added. Claims 1-21 are pending.

Claim Rejections - 35 USC § 112

2. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the recitation of "capable of" because it does not allow the metes and bounds of the claims to be ascertained. The original recitation of "specifically binds" is appropriate.

Claim 2 is vague and indefinite with respect to the description of the biosensor signal transducer. It is suggested that Applicant rewrites claim 2 as follow:

The biosensor according to claim 1, wherein the carbohydrate derivative is chemically bound or is bound via adsorption to <u>the</u> [a] surface <u>of the biosensor, which surface constitutes a signal transducer portion</u> [of a biosensor signal transducer].

Claims 14 and 21 are vague and indefinite because of the use non-idiomatic English. It is suggested that Applicant recites --Method of binding-- instead of "method to bind" to obviate the rejection.

Claim 15 is vague and indefinite with respect to the recitation of "a gold surface with a carbohydrate derivative". It is suggested that Applicant replaces "with" with --having-- to obviate the rejection.

Claim 16 is vague and indefinite because there is no step of binding of the protein, virus or cell to the carbohydrate on the biosensor. Without such binding, detection of the protein, virus or cell is not possible. The step of measuring and detecting is also vague and indefinite because it does not state what type of signal is being measured.

Claim 17 is vague and indefinite because a carbohydrate derivative comprising a spacer molecule is not supported by the specification. It is believed that Applicant is referring to the fact that the carbohydrate derivative is bound to the biosensor via a spacer molecule. If this is the case, claim 17 should be amended to reflect this relationship.

Claim Rejections - 35 USC § 103

3. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (US Patent No. 4,918,009) in view of Attridge et al (WO 90/01166) and Karube (EP 0215669).

Nilsson discloses a large number of carbohydrate derivatives which meet the limitations of the instant claims. Nilsson teaches carbohydrate derivatives synthesize by forming a glycosidic bond between glycosyl donors and glycosyl acceptors. The donor substance is a monosaccharide or oligosaccharide or a glycoside of a monosaccharide or oligosaccharide is caused to react with an acceptor substance which is an O-, N-, C- or S-glycoside consisting of a monosaccharide, oligosaccharide or a saccharide analog and at least one aglycon which is O-, N-, C- or S-

glycosidically bonded in the 1-position, in the presence of a glycosidase, the presence of a glycosidase, the α- or β- configuration being selected for the glycoside bond between the glycosyl group and the aglycon in the acceptor substance (column 3, lines 46-64). Nilsson further teaches that the donor substance may be derivatised at its reducing end with a glycosidically bonded organic substance. The organic substance may be aliphatic, aromatic, heterocyclic etc, and may be glycosidically bonded to the 1-position of the donor substance such as methyl, phenyl, p-nitrophenyl, o-nitrophenyl, 4-methylumbelliferyl glycosides (column 4, lines 44-68). Nilsson teaches that products obtained with alkyl glycosides (such as methyl, octyl, dodecyl glycosides) as acceptor substances may be directly or after chemical modification, can be coupled covalently to different polymers (dextran, polyethylene glycol, agarose, cellulose, silica etc) as well as to peptides, proteins, enzymes, lipids or analog thereof (column 6, lines 22-34). Nilsson also teaches that amino groups are readily convertible into several other reactive groups, such as isothiocyanate, diazo, N-bromoacetate or other groups, which directly or after chemical modification, may be used as spacer arm, and which are also useful as aglycon.

look @ this spacer arms in ref.

c/l 39—

Nilsson differs from the instant invention in failing to teach immobilized the carbohydrates on a biosensor.

Attridge et al disclose an optical sensor comprising a ligand immobilized on a gold surface for use in the detection of a protein, virus, or cell which is bound by said ligand. The ligand may be a specific carbohydrate. Surface plasmon resonance is used to measure binding on the gold surface. Page 5, lines 1-4 and 20-30; page 13, line 31 through page 16, line 12 and table 1.

Karube discloses a piezoelectric crystal biosensor having immobilized thereon a receptor material for the detection of microbes and cells. The receptor may be a sugar (carbohydrate). Page 3, lines 3-15; and page 16, lines 15-28.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbohydrates of Nilsson in the devices of Attridge and Karube because Nilsson teaches that his carbohydrates may be immobilized on solid carriers for use in diagnostic assays (column 7, lines 26-29, column 15, lines 10-13 and column 20, lines 34-39) and because the solid phase taught by Nilsson is seen to be functionally equivalent with the biosensor surface of Attridge and Karube, therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the carbohydrate derivatives of Nilsson in the biosensors of Attridge and Karube because Nilsson teaches that carbohydrates made from the method of his invention provides the advantage of a readily purified isomeric product mixtures. Nilsson also teaches that further chemical modification of the products before they could be coupled to proteins, lipids, etc. is not necessary.

Response to Arguments

4. Applicant's arguments filed 8/25/97 have been fully considered but they are not persuasive.

Applicant argues that Nilsson and Attridge et al do not teach binding of the carbohydrate to the biosensor via the aglycon portion. This argument is not persuasive because Nilsson taught the same carbohydrate derivatives as those of the instant invention, column 4, lines 2-17, and Nilsson taught coupling the carbohydrates to proteins or lipids (column 3, line 35) or to solid

carriers (column 7, line 28), and Attridge et al teach the use of sensor to immobilize a carbohydrate, therefore, a skilled artisan would have had a reasonable expectation of success in immobilizing the carbohydrates of Nilsson on the biosensor of Attridge et al because the solid carriers of Nilsson et al is seen to be functionally equivalent to the solid sensors of Attridge et al. Further, a skilled artisan, using immobilization methods well known in the art to immobilize the carbohydrates of Nilsson would have resulted in a surface having a carbohydrate immobilized via the aglycon portion because the carbohydrates of Nilsson are the same with those of the instant invention, therefore, they would be expected to have the same inherent binding properties.

The argument that the references do not teach functionalizing the surface of the biosensor with thiol compounds is not persuasive because both Nilsson and Karube et al teach chemically modifying either the carbohydrate or the surface of the sensor to facilitate the immobilization of the carbohydrates onto the sensor, and because the activation of the amino-, carboxyl- or thiol-groups is well known in the art, as indicated in the instant specification at page 5, (4th paragraph), therefore, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the gold surface in the biosensor of Attridge et al with thiol compounds through which the carbohydrates may be immobilized.

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday through Thursday, from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

BTN
December 8, 1997

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800